

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

FEB 1 0 2011

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Olivia Laird
Laird's Regulatory Consultants, Inc.
Estates at Shenstone Farm
17804 Braemar Place
Leesburg, VA 20175

Subject:

Vital Technologies

Vital Oxide

EPA Registration No. 82972-1 Submission Dated: February 8, 2011 Receipt Dated: February 8, 2011

Dear Ms. Laird:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is accepted with conditions.

### Amendment:

- Update the Container Disposal Language
- Add Residential and Commercial

### Conditions:

- 1. The "Refrigerated Storage Units" use directions should state that the unit is empty and disconnected when applying Vital Oxide to sanitize.
- 2. The directions for use that include must be qualified with a double asterisk, which connect it to the following statement that must appear on the label for this product.
  - \*\*This product is not to be used as a terminal sterilant/high level disinfectant on any surface of instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization of high level disinfection.
- 3. Revise "Influenza A (H1N1) Swine Flu" to read "Influenza A (H1N1) (formerly called Swine Flu)"

4. The Container Disposal language must be revised to read: Non-refillable. Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container.

### General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact me at <u>Henson.Wanda@epa.gov</u> or call (703) 308-6345.

Sincerely

Wanda Y. Henson

Acting Product Manager - Team 32 Regulatory Management Branch II Antimicrobials Division (7510P)

Disinfects As It Cleans • Eliminates Odors • Fragrance Free VITAL OXIDE provides hospital disinfection, sanitization of food contact surfaces, mold & mildew prevention, broad spectrum cleaner & odor

ARFAS OF USE INCLUDE: homes, vehicles, schools & daycare, gyms & locker rooms, sports gear, hospitals, nursing homes, laundry rooms, veterinary, pharmacies, ambulances, barber shops, laboratories. restaurants, boats, ships, federally inspected meat & poultry processing plants, farms, animal pens and poultry houses, egg processing premises, hatcheries, swine premise sanitation, refrigerated storage units, airplanes, trains, trucks, buses & automobiles. Use as a mold & mildewstat on hard non-porous surfaces such as tile, and porous surfaces such as fabric.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Test fabric for color fastness. Contains a dilute oxidizing agent. Do not mix with vinegar or acidic cleaners.

Pre-cleaning Instructions: Remove gross filth and heavy soil by cleaning. Spray VITAL OXIDE straight onto soils, scrub and wipe clean with a dry paper towel or cloth. For cleaning floors add one cup VITAL OXIDE per gallon of water in bucket and clean with sponge, mop or

To Disinfect Hard Non-porous Surfaces: For disinfecting precleaned hard non-porous surfaces such as glass, plastic, painted wood, faminate, chrome, stainless steel, polyurethane coated hardwood floors, glazed ceramic tile, sealed concrete & linoleum floors. Types of items include: appliances, bed frames, cabinet handles, wheelchairs, child car seats, counters, cribs, doorknobs, tables, tubs, exterior toilet surfaces, faucet handles, handrails, jungle gyms, keyboards, light switch covers, patio furniture, showers, sinks, stovetops, telephones, toys, walls, waste containers. Apply VITAL OXIDE full strength to pre-cleaned hard nonporous surfaces, wetting thoroughly with spray, sponge, mop, or by immersion in solution. Allow surfaces to remain wet for 5 minutes for virus inactivation - 10 minutes for bacteria disinfection. For immersion replace solution daily, or more frequently if it becomes significantly soiled or diluted. For machine application, see the Manufacturer's Bulletin specific for that equipment when using Vital Oxide. To Prevent Mold or Mildew on Floors, Walls, Ceilings & Fabric: Remove as much surface dirt, mold, or mildew as possible by cleaning. Then spray on VITAL OXIDE from a distance of 12 inches until visibly wet and let air dry. To Deodorize: VITAL OXIDE works by oxidation, not by masking of odors. Eliminates odors caused by fire smoke. tobacco smoke, musty odors, stale-cooking odors. Simply spray, fog or wipe on full strength and let air dry to provide long lasting residual deodorizing action. When fogging apply I quart per 2000 cubic ft. following fogger manufacturer's directions for use. VITAL OXIDE must come into contact with the cause of the odor to be effective. For pet urine stains in carpet, blot urine as dry as possible then saturate stain with VITAL OXIDE through carpet pad.

To Sanitize Food Contact Surfaces: Stophylococcus gureus (ATCC 6538) and Escherichia coli (ATCC11229) 99.999% sanitization of food contact surfaces. Mix I part VITAL OXIDE to 12 parts tap water. For glassware, utensils, cookware, and dishware: Scrape and pre-wash, then wash with a good detergent. Rinse with potable water, then sanitize by immersion in VITAL OXIDE for I minute (or longer if specified by government sanitary code) Place on a rack or drain board to air dry. Do not rinse or wipe. Food Contact Immobile Surfaces: (food processing equipment, counter tops, tables, appliances) Remove all gross food particles and soil by cleaning and rinse with potable water. Apply VITAL OXIDE by wetting thoroughly and let stand for 1 minute. (or longer if specified by government sanitary code) Let surfaces drain and air dry. Do not rinse or wipe.

## VITAL OXIDE

### Residential, Commercial & HOSPITAL DISINFECTANT

KILLS HARMFUL BACTERIA 99.999% SANITIZATION OF FOOD **CONTACT SURFACES** 



No rinse required sanitizer for food contact surfaces (D-2) Kills Harmful Bacteria MOLD &: MILDEW REMOVER PREVENTS MOLD & MILDEW ON HARD SURFACES & FABRIC

### HEAVY DUTY ODOR ELIMINATOR

#### **VITAL-OXIDE KILLS:**

MRSA (Methicillin-resistant Staphylococcus Aureus), Pseudomonas aeruginosa, Escherichia coli, Salmonella enterica, Staphylocóccus aureus, Legionella pneumophila. Aspergillus niger, Norovirus/Feline Calicivirus as surrogate)
Human Immunodeficiency virus type (HIV-12 MENTS Enterobacter aerogenes, Listeffe manocytogenes, Acinetobacter baumannii, Rotavirus, Respiratory Syncytial Virus, Influenza A (H1N1)Swipe Flu, Hepatitis B, Hepatitis C

Under the Federal Insecticide. Fungicide, and Rodenticide Act amended, for the pesticide,

ACTIVE INGREDIENTS: Chlorine Dioxide. 1ecistered and 0:200% Reg. No. Alkyl (68% C<sub>12</sub>, 32% C<sub>14</sub>) dimethyl ethylbenzyl ammonium chloride......0.125% OTHER INGREDIENTS.....99.550% Total......100.000%

### KEEP OUT OF REACH OF CHILDREN CAUTION

See side panel for additional precautionary statements

NET CONTENTS: 128 oz.

To Sanitize Carpet: For synthetic carpet fibers such nylon, olefin, or polypropylene - not intended for use on wool carpet. Test for color fastness in an inconspicuous area. Carpet should be clean or free of excessive soil before applying. Mix 1 part Vital Oxide to 5 parts water. Apply by sprayer at a rate of 1.7 gallons per 10 sq. yards (approx 22oz per sq. yd). Vital Oxide must come into contact with contaminate to work. Allow to dwell for 10 minutes. Do not rinse, use an extraction wand and dry stroke carpet to remove excess moisture. Carpet can air dry or fans may be used if carpet needs to dry faster. To Disinfect Farm Premises, Poultry Houses, Animal Pens & Vehicles: Remove all animals and feed from premises, vehicles, and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with VITAL OXIDE for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Allow to air dry. Ventilate buildings, cars, boats, and other closed spaces. Drain any pooled product and/or rinse standing product with potable water. Do not house livestock or employ equipment until treatment has been absorbed or dried KILLS HIV-LHBV.AND HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces /objects with blood or body fluids and surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency virus type1 (HIV-1) (associated with AIDS), Human Hepatitis B virus, and Human Hepatitis C virus, SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-I. HBV: and HCV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS PERSONAL PROTECTION: When handling items soiled with blood or body fluids use disposable latex gloves, gowns, masks, or eye coverings. CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should

be autoclaved and disposed of according to Federal. State and local regulations for infectious waste disposal. CONTACT TIME: Allow surfaces to remain wet for 5 minutes. This contact time will not control bacteria.

STORAGE AND DISPOSAL: Store in original closed container in a cool, dry place away from heat and open flame. Refill this container only with Vital Oxide or a dilution of this product as allowed in directions for use. Do not reuse this container for any other purpose. Container Disposal: Rinse and offer empty container for recycling. If recycling is not available discard container in trash. Wastes resulting from the use of this product may be Sdisposed of on site or at an approved waste disposal facility. Discard excess or used VITAL OXIDE solution in drain with running water.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS & DOMESTIC ANIMALS Causes moderate eye irritation. Avoid contact with eyes

FIRST AID

Hold eye open and rinse slowly with water 15-20 mins. Remove contact lenses after first 5 mins, and continue rinsing. Call a Poison Control Center or doctor for treatment advice. Have product container or label with you when calling a poison control center or doctor, or going for treatment,

Manufactured by: Vital Technologies, Inc. PO Box 9932 W. Palm Bch, FL 33419 Customer Service: 1-800-303-5405 www.vitaltechnologies.com EPA Reg. No. 82972-1 EPA Est. No. 85804-NC-1: EPA Est. No 29909-CA-1 (See batch code for actual establishment number) NOTICE: Seller expressly warrants that the product conforms to its chemical description. There are no other warranties associated with the sale of this product.